

## **EXHIBIT G**



Gynecare  
**Gynemesh™ PS**

Nonabsorbable PROLENE™ Soft Mesh

Ikke-resorberbar blød PROLENE™-meche  
Niet-resorbeerbaar PROLENE™ soft mesh  
Resorboitumaton pehmeä PROLENE™-verkko  
Treillis PROLENE™ non résorbable, souple  
Nicht-resorbierbares PROLENE™ Soft-Netz  
Rete non assorbibile in PROLENE™ morbido  
Rede não absorvível PROLENE™ Soft  
Malla blanda PROLENE™ no absorbible  
Icke absorberande PROLENE™ mjuk nät  
Μη απορροφίσιμο μαλακό πλέγμα PROLENE™  
不可吸收的PROLENE™柔软网片  
PROLENE™不可吸收軟網  
비흡수성 PROLENE™ 소프트 메쉬

ETHICON  
Women's Health & Urology

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San Lorenzo, Puerto Rico 00754

Made in U.S.A.  
389766

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## **GYNECARE GYNEMESH™ PS**

Nonabsorbable PROLENE™ Soft Mesh

ENGLISH

### **DESCRIPTION**

GYNECARE GYNEMESH™ PS is constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE™ Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, LLC). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE™ monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE™ mesh.

GYNECARE GYNEMESH™ PS is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

### **INDICATIONS**

GYNECARE GYNEMESH™ PS is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

### **INSTRUCTIONS FOR USE (APPLICATION)**

It is recommended that sutures, staples or other appropriate fixation devices be placed at least 6.5 mm (1/4") from edge of the mesh. Some surgeons prefer to suture into position an uncut section of mesh that is considerably larger than the defect. When the margin sutures have all been placed, the extra mesh is trimmed away.

### **PERFORMANCE**

Animal studies show that implantation of PROLENE™ mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

### **CONTRAINDICATIONS**

When this mesh is used in infants, children, pregnant women or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

**WARNINGS/PRECAUTIONS/INTERACTIONS**

Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing GYNECARE GYNEMESH™ PS for pelvic reconstruction. Acceptable surgical practices should be followed for the management of infected or contaminated wounds.

The use of GYNECARE GYNEMESH™ PS in contaminated wounds should be used with the understanding that subsequent infection may require additional surgical procedures such as removal of the mesh.

**ADVERSE REACTIONS**

Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.

**STERILITY**

The product is sterilized by ethylene oxide. **DO NOT RESTERILIZE.** Do not use if package is opened or damaged. Discard opened, unused mesh.

**STORAGE**

Recommended storage conditions: below 25°C, away from moisture and direct heat. Do not use after expiry date.

**HOW SUPPLIED**

GYNECARE GYNEMESH™ PS is available in single packets as sterile, clear sheets with blue stripes.

